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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,273	10/31/2003	Ian Chan	COD-5031	2051
27777	7590 11/17	05	EXAMINER	
PHILIP S. J		DEAK, LESLIE R		
JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Then

	Application No.	Applicant(s)				
Office Assistant Community	10/699,273	CHAN, IAN				
Office Action Summary	Examiner	Art Unit				
	Leslie R. Deak	3761				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 31 Oc	ctober 2003.					
, _	action is non-final.					
, <u> </u>	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
• " •	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) Claim(s) 1-30 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-30</u> is/are rejected.						
7) Claim(s) <u>7-30</u> is/are rejected. 7) Claim(s) is/are objected to.						
· — · · · · — · · · · · · · · · · · · ·	7)					
o) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner.						
10) $\boxtimes$ The drawing(s) filed on <u>31 October 2003</u> is/are: a) $\square$ accepted or b) $\boxtimes$ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
<ol> <li>Certified copies of the priority documents</li> </ol>	1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Notice of Informal Patent Application (PTO-152)						
Paper No(s)/Mail Date 12/15/03.	6) Other:					
S. Patent and Trademark Office						

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#### **DETAILED ACTION**

### **Drawings**

1. The drawings are objected to because they are generally of poor quality with unclear lines and extraneous marks. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,883,113 to Kolb in view of US 5,342,025 to Hwang.

Kolb, in the specification, and the figures, discloses the valve substantially as claimed. In particular, Kolb discloses a valve 10 with a body portion 12, an inlet 14 and outlet 16 disposed opposite one another (see FIG 1, column 2, lines 15-30). The valve body comprises a generally spherical chamber 48 that holds a spherical ball 50 which has an outer diameter less than the inner diameter of the valve chamber 48 (see FIG 1). When valve chamber 48 is expanded by loosening nuts 48, allowing ball valve to rotate in the chamber 48. The ball 50 further comprises a recessed channel 52 and a bore through the ball (see FIGS 5-6). When the ball is oriented such that the bore is longitudinally contiguous with the inlet and outlet, fluid flows through the ball.

Kolb fails to disclose that the valve housing and the valve member comprise a magnetic material. Hwang discloses a fluid flow control valve with inlet 100, outlet 200, stationary valve portion or housing 50, and smaller-diameter movable valve portion 40. Stationary valve portion 50 is connected to magnet ring 60 to create a magnetized housing (see column 4, lines 15-35, FIG 5). Movable valve portion 40 is connected to magnet ring 30 to create a magnetized valve member, and is covered by tubular seat 10. Changing the orientation of magnet ring 60 forces the movement of valve member 40 and magnet ring 30 to allow or prevent fluid flow through the valve. The amount of fluid passing through the valve may be controlled by selecting the orientation of the

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magnet ring 60 between the fully opened and closed positions while preventing leaks through the valve.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ball valve disclosed by Kolb with a magnetic housing and magnetic valve member, as disclosed by Hwang, in order to provide selectable fluid control through the valve with minimal leaks, as taught by Hwang.

With regard to claim 2 drawn to the location and shape of the magnetic members, Hwang discloses that the housing or stationary portion of the valve comprises magnetized portions. It has been held that rearranging, duplicating, and changing the shape of the parts of an invention disclosed in the prior art involves only routine skill in the art. See MPEP 2144.04.

With regard to claims 3-9 drawn to the charge and materials used for the device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the claimed materials and charges for the invention, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07.

With regard to claims 10-12 drawn to the operation of the invention, such statements are held by the examiner to be recitations of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.

Applicant's claim preamble suggests that the claimed valve is suitable for shunting fluid flow within a patient's body. Examiner holds that the preamble is not integral to the understanding of the body of the claim, and is thus not limiting. See MPEP 2111.02. The combination disclosed in the prior art is capable of being deployed to shunt patient fluid in an external shunt system, or modified in size to be implanted within a patient.

4. Claims 15-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,883,113 to Kolb in view of US 5,342,025 to Hwang as applied above, further in view of US 4,615,691 to Hakim.

Kolb and Hwang disclose the device substantially as claimed with the exception of a second check valve in fluid communication with the magnetic ball valve.

Hakim discloses a cerebrospinal fluid shunt with a an inlet end 18 outlet end 20 and two valves 12 and 14. Valve 12 is a one-way check valve that prevents fluid from returning to the inlet end of the catheter while valve 14 is an adjustable valve (see FIG 1, column 3, lines 43-67). Hakim does not disclose that the second valve is disposed within the one-way valve. However, rearranging the parts of an invention disclosed in the prior art involves only routine skill in the art. See MPEP 2144.04.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a second valve to the fluid control system disclosed by Kolb and Hwang in order to prevent fluid return to the inlet end, as taught by Hakim.

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With regard to claim 16, rearranging, duplicating, and changing the shape of the parts of an invention disclosed in the prior art involves only routine skill in the art. See MPEP 2144.04.

With regard to claims 17-23 drawn to the charge and materials used for the device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select the claimed materials and charges for the invention, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07.

With regard to claims 24-26 drawn to the operation of the invention, such statements are held by the examiner to be recitations of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.

With regard to claims 27 and 28 drawn to the programmability of the check valve, it is the position that any valve is capable of being programmed. That is, the spring bias of the valve may be set at a factory tension or adjusted by the user before implantation. The recitation that an element is capable of (or able to, as in "programmable") performing a function is not a positive limitation.

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#### Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 3,166,083 Girden

i. Magnetic ball valve actuated by orientation

b. US 3,373,498 Chabbert

ii. Freely rotating magnetic compass

c. US 4,289,165 Fredd

iii. Equalizing ball valve with channel

d. US 5,894,856 Swenson et al

iv. Magnetic ball valve actuated by change in orientation

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eslie Deak

Patent Examiner Art Unit 3761

10 November 2005